

Nexus 10W Laser System



Operating Instructions

Clearly Beautiful Nails LLC
Nexus 10W



	Model: Nexus 10W 980nm±10nm, max. 10W
Manufacturer: Wuhan Gigaa Laser Optronics Technology Co., Ltd. II-4-502, International Enterprise Center Guanggu Road Wuhan 430074 PRC TEL: 011-86-27-67848871 FAX:011-86-27-67848873	The CE mark is shown in a large, bold, black font. To its right, the number '0482' is written in a smaller, bold, black font.

Manufacturer:

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II-4-502, International Enterprise Center
Guanggu Road
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Medical Device: Nexus 10W 980nm \pm 10nm, 10W

The **Nexus 10W** meets the requirements of the Annex II of the **Directive 93/42/EEC** and is classified subject to **Annex IX rule 6** as a medical device of Class **IIB**.

The product is designed in conjunction with the following safety standards:

EN 60825-1	Safety of IR Laser products
EN-60601-1	Medical electrical equipment
EN 60601-1-2	Medical electrical equipment – 2. Collateral Standard
EN 60601-1-4	Medical electrical equipment – 4. Collateral Standard
EN 60601-2-22	Medical electrical equipment – Part 2: Particular requirements for the safety of diagnostic and therapeutic IR Laser equipment

This declaration is based upon a Quality System meeting the requirements of DIN EN ISO13485:2003 and DIN EN ISO 9001:2000.

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1 Warnings and safety precautions

THE USER'S MANUAL AND INSTRUCTIONS SUPPLIED WITH THIS IR LASER MUST BE FULLY READ AND UNDERSTOOD BEFORE OPERATING THIS DEVICE

**Visible and Invisible Laser Radiation
Avoid Eye or Skin Exposure to
Direct or Scattered Radiation**

CLASS 4 IR LASER DEVICE

IR DIODE 980nm+/-10nm, 10W

GUIDE LIGHT 635nm+/-10nm, 4mW (max.)

EN 60825-1:2003 EN 60601-2-22:1996

WARNING: Always wear protective eyewear when using this device.

The optical power IR diode-based output from this Laser system can cause severe eye damage or other injuries. Always wear protective eyewear when using this unit. Exercise extreme caution to prevent injury.

This equipment is intended for use by trained physicians or licensed healthcare practitioners only, and should only be operated by qualified personnel who have familiarized themselves with the operating parameters of this product prior to use.

The **Nexus 10W** IR Laser contains a class 4 IR light source according to Directives EN 60825-1:2003.

A class 4 IR Laser is hazardous to the eye from both direct beam and diffuse reflection of the beam. It also represents significant skin and fire hazards.



Danger: Do not use the unit near flammable anesthetics or other flammable substances.

Avoid eye or skin exposure to direct or scattered radiation. Take all necessary precautions in areas in which the laser is being used.

Near infrared light (980nm) from the **Nexus 10W** can pass through the transparent components of the eye and on the retina at the back of the eye. This can there cause an accidental retinal burn.

Only protective glasses designed for protection from continuous IR Laser radiation at a wavelength of 980nm +/-10nm with an optical density of **OD ≥ 4** should be used. Glasses not designed to this specification are not suitable for eye protection. Suitable glasses are available from your CBN representative



ATTENTION: Do not stare into the aiming beam or view the aiming beam directly through optical instruments. Avoid direct exposure to the aiming beam.

Avoid placing reflective material, such as metal and glass, into the beam.



ATTENTION: Accidental irradiation to other than the target tissue may result in tissue burn.



ATTENTION: The Nexus 10W is only to be used in combination with a footswitch or handswitch and light delivery systems with the device.



ATTENTION: Please avoid touching the patient and the footswitch or handswitch connector socket simultaneously.

Note: A minimum distance of 25 cm should be maintained between the ventilation slots and walls.

To prevent the risk of electrical shock, do not remove the cover. All servicing should be done by CBN or by qualified personnel authorized by CBN. After the end of the warranty period sufficiently qualified persons can also do servicing.

The equipment should be routinely inspected and maintained in accordance with the instructions given in the maintenance section of this manual.

Disconnect the unit from power supply before cleaning and disinfecting.



Caution: Use controls or adjustments or performing procedures other than those specified in this manual may result in hazardous radiation exposure.



Note: IR laser equipment when not in use should be protected against unqualified use by removing the key from the footswitch or handswitch connector.

2 Post-Market Quality Monitoring

CBN maintains procedures that review devices in their post-production phase and to

implement any necessary corrective action(s). This medical device vigilance system is designed to improve the protection of the health and safety of patients, users, and others. This is achieved by the evaluation of reported incidents, and where appropriate, the dissemination of information to prevent repetitions, and/or alleviate the consequences of adverse incidents.

Organizations and individuals involved in the purchasing of medical devices and in the provision of healthcare should be aware that their co-operation is vital in providing the first link in the vigilance chain. This includes organizations and individuals responsible for providing calibration and maintenance of medical devices.

The following incidents should be reported to CBN immediately upon becoming known:

Any malfunction or deterioration in the characteristics and/or performance of a device, or inadequacy in the labeling or instructions for use, which led to or might have led to death or serious injury of a patient or user.

Reports should be made to:

CBN Inc. – 1759 Country Club Drive, Cherry Hill, New Jersey 08003

TEL: 888-510-2410
FAX: 866-275-0516
E-mail: Michael@ClearlyBeautifulNails.com

3 Product description

The **Nexus 10W** Infrared (IR) Laser System is a compact, air-cooled unit. It is a complete self-contained instrument, which includes a high efficiency power supply, a microprocessor controller, adjustable light output with automatic power stabilization, (fan cooled), as well as a switch panel and LCD screen display panel designed to be user friendly. The system includes a high power IR Laser, safety features and an SMA fiber output connector. The system includes Lithium batteries. It can work for 1 hour with no external power input and at maximum power output **in pulse or CW in intermittent mode** (see Section 9: The Lithium-ion battery).



Warning: Do not damage the Lithium-ion battery. A damaged battery can cause an explosion or fire and can result in personal injury and/or property damage.

The IR diodes are made from GaAlAs semiconductor material for high output and superior reliability. The IR diodes are enclosed in a rugged, factory-aligned, replaceable, environmentally protective module. High-capacity fans eliminate the need for water-cooling and assure low maintenance and reliable laser operation. The diodes convert

electric energy into coherent IR laser radiation with a wavelength of 980 +/-10nm (pilot beam: 635nm+/-10nm).

The **Nexus 10W** has 3 modes of operation, CONTINUOUS, SINGLE PULSE MODE and CONTINUOUS PULSE MODES.



Attention: The output energy of the IR Heap Laser lies above the safe level for compatibility of the eye and can lead to irreversible eye damage. In order to avoid eye damage, all persons in the area have to wear the protective eyewear.

The **Nexus 10W** model has a maximum optical output power of 10W at 980nm.

The **Nexus 10W** meets the intent of Directive EN 60601-1-2:2001:

Electromagnetic Compatibility Requirements and Tests. Compliance was demonstrated to the following specifications as listed: CISPR 11 (1990), IEC 801-2 (1991-04), IEC 801-3(1993), IEC 801-4 (1988) and IEC 801-5 (1992-07).

Nexus 10W laser can therefore only be used in a professional clinical environment. Any operating and servicing is to be done only by qualified, licensed personnel.

Potential electromagnetic or other influences between the equipment and other devices cannot be completely excluded despite appropriate design precautions. Inform CBN in such a case.

Accidental irradiation of tissue other than the target tissue may result in a burn or vaporization regardless of the wavelength. Surrounding the target area with moist drapes or saline-soaked cotton will keep it moist and greatly reduce this potential hazard. Care and precision in aiming and applying laser energy is of paramount importance.



WARNING:

Never handle the fiberoptic cable using a clamp as doing so can result in an unsafe use condition. Use of a clamp can result in the fiberoptic being bent at sharp angles or fiber damage that, in turn, can also result in an unsafe use condition. The fiberoptic can break causing a burn in the protective jacket and the release of IR laser energy. If undetected, this condition can result in a burn or ignition of flammable materials.

Must keep the handpiece with SMA 905 connector clean. Otherwise, the internal IR diode module could be destroyed by thermal build-up.

4 Technical Specifications

Nexus 10W	10W \pm 10% with 980nm diode
IR Laser Source	GaAlAs semiconductor diode
Wavelength	980 \pm 10nm
Application / Light delivery systems Core Size (use only approved handpiece systems)	600 μ m diameter fiberoptic cable
Numerical Aperture	NA = 0.22 – 0.48
Fiber Connector	SMA 905
Exposure Mode	Continuous (CW) / Pulse
Pulse Duration	Variable 1ms to 1000ms or continuous
Power Control	Built in power monitoring circuit
Aiming Beam; Aiming Power	635nm \pm 10nm; 4mW (max)
Safety Standards	EN 60601-1 :1990+A1 :1993+A2 :1995 EN 60601-1-2 :2001 EN 60601-1-4 :1996+A1 :1999 EN 60601-2-22 :1996 EN 60825-1 :2003
IR Laser Class	4

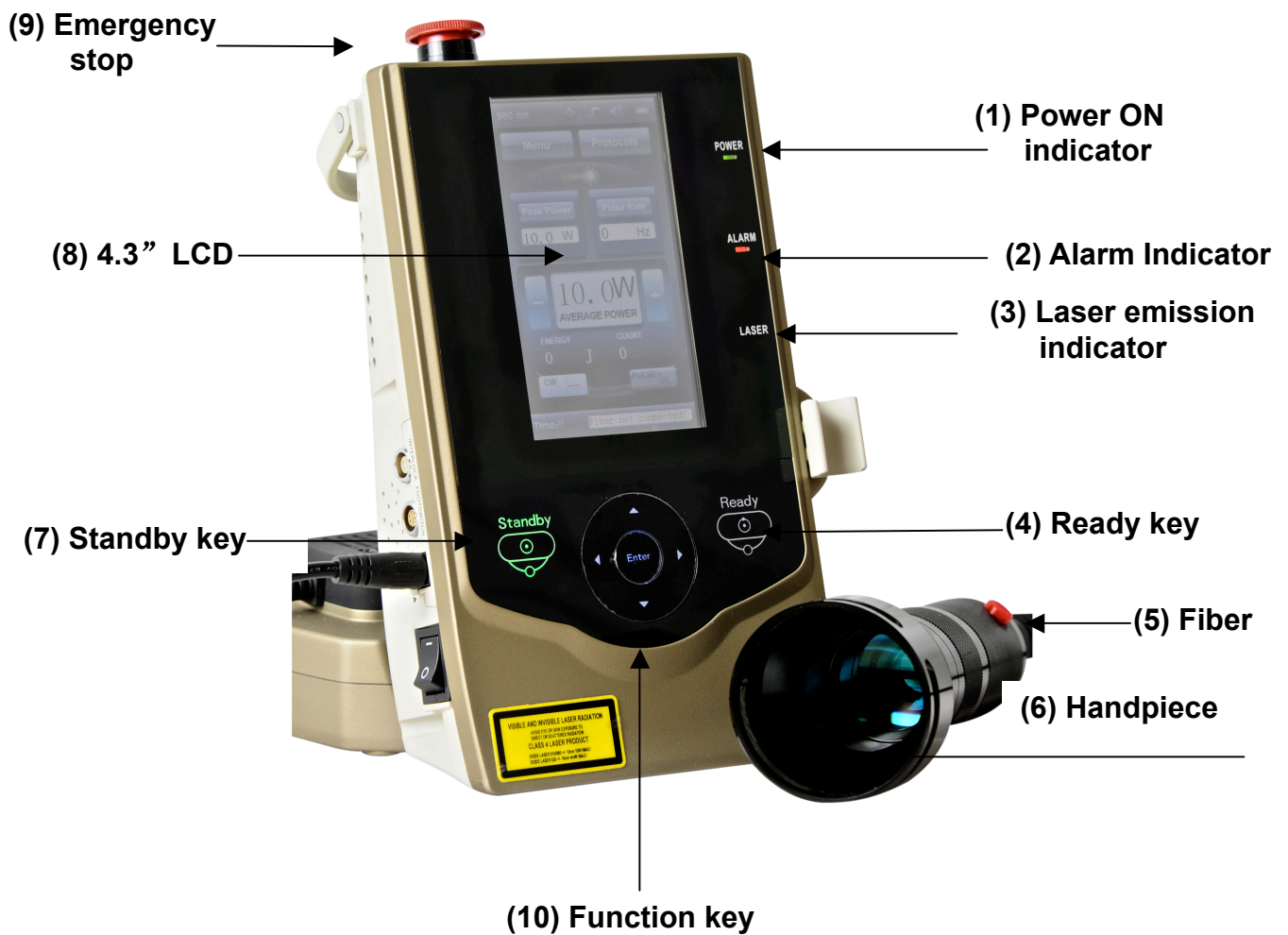
Power Supply	DC26V/4A. Use SINPRO MPU100-102 desktop power supply adapter
Lithium-ion battery	22.2V/2.2AH
Cooling	Air cooling

Footswitch & Handswitch Safety Standards	EN60204-1 EN60947-5-1 VDE0660 Part200 IEC 947-5-1 Safety type IP68 EN 60529
Product Class	1

Dimensions	204 mm x 120 mm x 76 mm (HxWxD)
Weight	2 kg
Operating Temperature	10 °C ~ 40 °C
Storage/Transport Temperature	-10 °C to +55 °C
Humidity	Storage/Transport: 10% - 80% Operating: 30% - 60%

5 PANELS, CONTROLS and LABELS

5.1 Panels and Controls



Front of Nexus 10W IR Laser System

(1) Power ON indicator — the indicator is illuminated when power is ON

(2) Alarm Indicator — the indicator light in case of malfunction

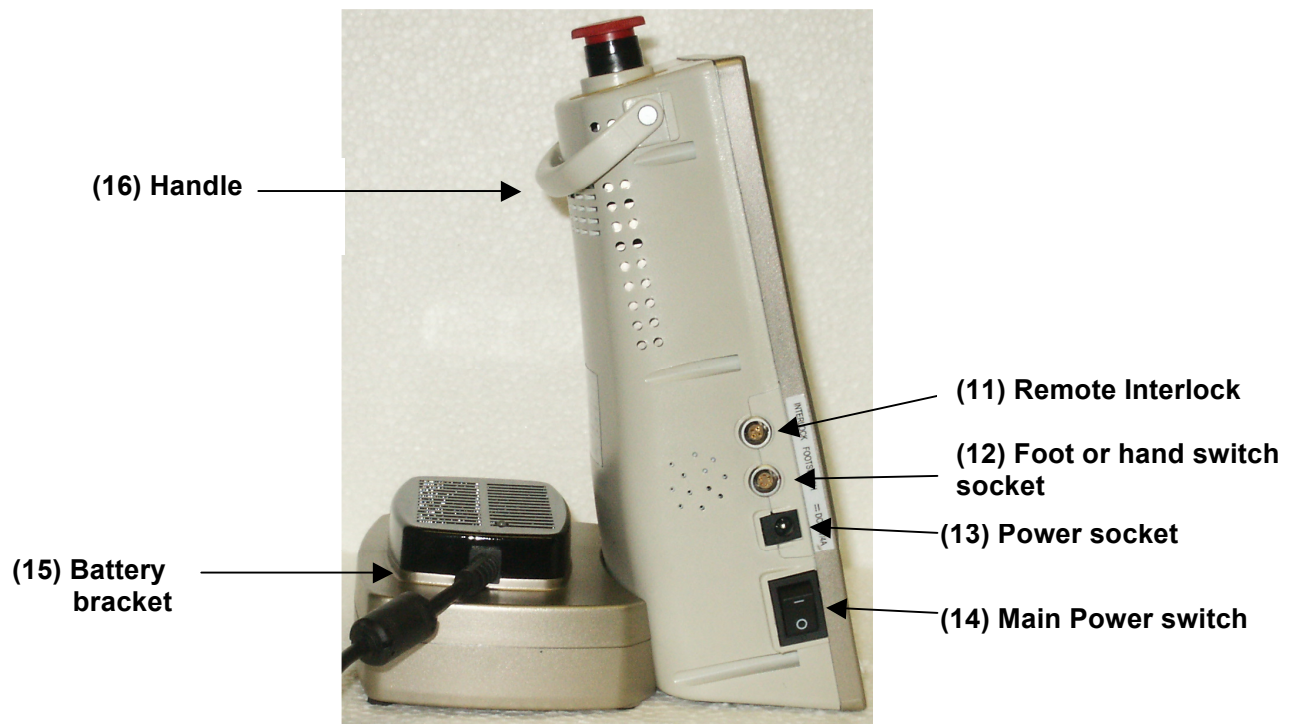
(3) Laser emission indicator — the indicator is ON when laser is firing

(4) Ready key — system into “READY” status; only in this status laser can emit

(5) Fiber —core $\geq 400\mu\text{m}$, NA=0.37

- (6) Handpiece**— Houses laser aperture from the fiber optic cables
- (7) Standby key** — system into “STANDBY” status
- (8) 4.3”LCD** — touch screen that displays system and laser information
- (9) Emergency stop** — stops laser emission when depressed
- (10) Function key** — sets laser parameters:
 - Set laser power
 - Set laser pulse parameters
 - Set options
 - Select treatment protocol

Left View of Nexus 10W IR Laser System

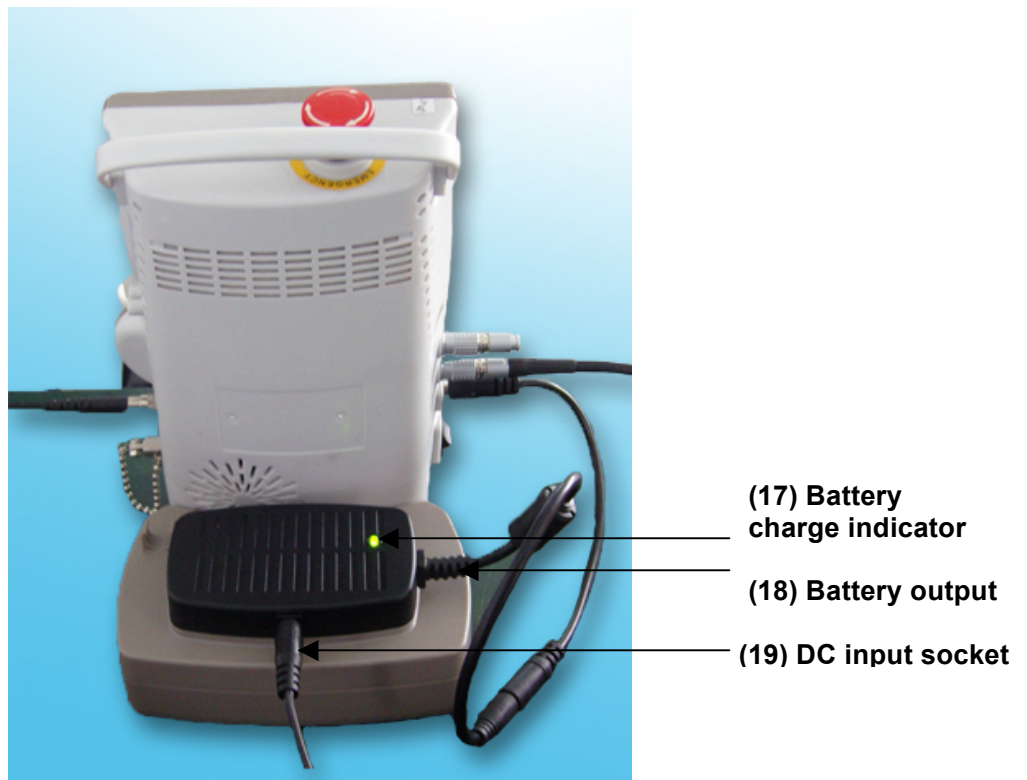


(11) Remote interlock - Can be connected to the room door so the laser will stop in the event of entry during lasing

(12) Foot or hand switch socket

- (13) **Power plug** — DC 26V/4A
- (14) **Main Power switch** — turns system power on (“1”) or off (“0”)
- (15) **Battery bracket** —houses Li-Ion rechargeable battery
- (16) **Handle**

Rear View of Nexus 10W IR Laser System



- (17) **Battery charge indicator** — the indicator light is orange when battery is charging and the indicator light turns to green when the battery is fully charged
- (18) **Battery output** — DC 24V
- (19) **DC input socket** — use the supplied AC-DC adaptor; input is 26V/A

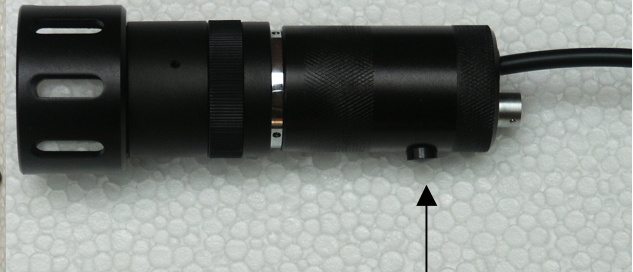
View of Nexus 10W IR Laser System Foot and Hand Switch



Foot Switch



Handpiece





Hand Switch

5.2 Labels

IR Laser Aperture



Certification and power rating label

Wuhan Gigaa Optonics Technology Co., Ltd.					
Name		Nexus 10W			
Model	10W	SN	GA09-C142	Manufactured	14/08/09
Max Laser Output Power		10W		Laser Wavelength	980nm
Rated Voltage		== DC 26V/4A		Rated Power Input	100W
Safety Classification				Laser Classification	4
Registered Number		 0482			

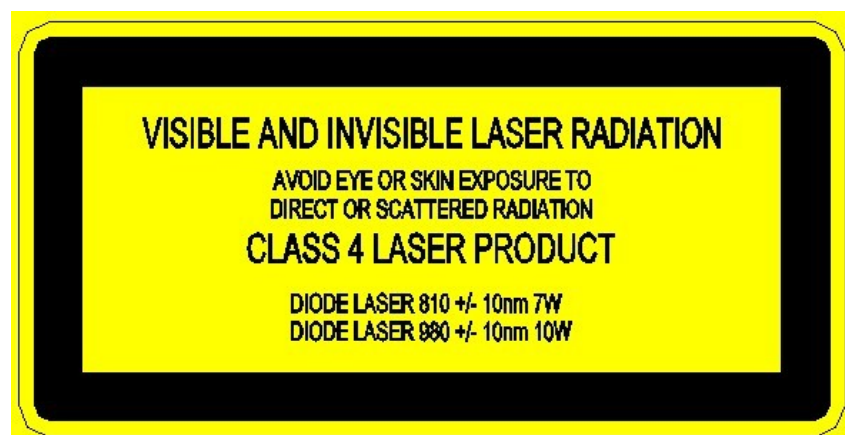
Model: Nexus 10W 980nm. Input Voltage: DC26V/4A

Danger and Warning

IR LASER 980nm ± 10 nm, 10W

GUIDE LIGHT 635 ± 10 nm 4mW (max.)

Example:



IR Laser Warning



PAY ATTENTION TO ACCOMPANYING DOCUMENTS



PROTECTIVE GROUND CONDUCTOR



CE Mark:



Type B Equipment



5.3 Description of controls, display and connectors

Display	<p>Display indicates:</p> <ul style="list-style-type: none"> - Unit status (Ready or standby) - Treatment mode (Continuous Mode, Pulse Mode) - Treatment parameter (Energy, Pulse Parameter) - Laser wavelength - Laser power setting - System message - Remaining battery power - System status <p>NOTE: settings of the unit can be changed using function key or touch screen.</p>
Function KEY	<ul style="list-style-type: none"> -Ready and standby -Treatment protocol select -UP and Down button -Enter / Return -Set options
Touch screen	Same as Function KEY
Set pulse parameter	<p>Laser parameters</p> <p>Repeated Pulse Mode:</p> <ul style="list-style-type: none"> -On Time – pulse length 1ms-1000ms -Off Time – interval between pulses 1ms-1000ms
Optical power output	SMA handpiece connector located on the right panel is the high power light output port
IR Laser warning	An audible signal will be emitted while the laser is active
Power knob	Power knob will allow the user to select the desired average power output
Emergency stop	<p>Pressing red button on top of unit will instantly shut down the laser and an error message will appear on the display. In this case it switches into the “Standby” mode. Use this button for emergency shut down only.</p> <p>Attention: Using emergency switch to shut down laser does not shut down the entire system.</p>
Main power switch	Unit is equipped with a main power switch and standard power entry module located at the left panel. On (“1”) / Off (“0”).
Power supply	Operator is allowed to use the laser with the supplied electrical power configuration only. See section: “Power Supply”. Before plug in power supply check all connections.

Foot or hand switch (6 PIN interlock)	Foot or hand switch must be connected to unit via 6 PIN interlock socket at right side of the unit. The red mark on the socket is to correspond to the red one on the nut. Laser radiation emission starts by depressing the foot or hand switch. Laser emits radiation for selected treatment time if the TIMER option has been activated. Treatment can be interrupted at any time by releasing the foot or hand switch. Treatment can be resumed by pressing the foot or hand switch again.
Interlock light delivery system and door interlock (4 PIN interlock)	If the interlock plug is not plugged in properly, the laser will not work and an error message will appear on the display "Interlock-error". Interlock connectors are located on the right side of the unit. A remote interlock switch can optionally be connected via this socket. This can be fitted to the treatment room door. Unit remains inoperative until this interlock switch is closed or the special blanking plug is used. <u>Attention:</u> Danger of electrical shock or damage. Do not connect the interlock to a power source.
Light delivery system	The laser can be used with light delivery systems with a core diameter of the fiber: $\geq 400\mu\text{m}$. The use of fibers with a smaller core diameter, fibers of lower quality material or fiber optic light delivery systems not approved by CBN can result in both damage to the system and potential laser safety hazards and will invalidate the warranty.

Display	Possible cause	Suggested action
Black display	Main power switch off	Switch on the main power switch
Black display	Other reasons	Service required
*** High Temperature ***	Overheating for a short time	Laser changes to standby mode, stop alarm until the proper operating temperature is reached
*** Laser Overheated ***	Cooling system failure	Service required
Door interlock	Door interlock not complete	Connect door interlock again; pay attention to the red mark
Door interlock	Door interlock failure	Check and repair door interlock system
Door interlock	Blanking plug not complete	Connect blanking plug again; pay attention to the red mark
Door interlock	Blanking plug failure	Change blanking plug; available from CBN
Laser current high	Application system failure	Change application system

Laser current high	Laser damaged	Service required
Battery power is low	Battery warning	Charge battery

6 Operating instructions



Attention: All personnel must wear protective eyewear to eliminate the risk of eye damage when operating the laser system

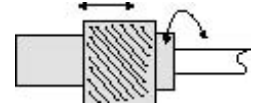


Caution: Use of the Nexus 10W in any way other than described in the operating instructions can lead to dangerous radiation exposure

The operator must care that the treatment room is properly labeled and that nobody can enter the treatment room without wearing protective eyewear.

6.1 Preparing unit before operation

Plug in the foot or hand switch cable into the 4-PIN-interlock-connector on the right side of the unit. The red mark on the socket is to correspond to the red one on the nut. Plug either the interlock-plug or the door-interlock-cable in the 2-PIN-interlock-connector at the right side of the unit. Connect a CBN delivery system or a laser probe approved by CBN for the use with the system to the SMA connector located on the right panel.



Built up the power supply like described in section: "Power supply".

Connect an approved light delivery handpiece system by the SMA connector.

Screw the cup nut till hand-tight.

The light delivery handpiece system is completed connected if there is no axial and radial clearance and no turn of fiber is possible.



Caution:

Nexus 10W must be placed vertically with the battery in place and the bottom panel must be level

6.2 Powering up system

Plug in the power supply (see Section: "Power supply"). To power up unit, first turn on the main power switch to the "1" position. The display shows the logo picture for 2 seconds.



After this interface, the system requires the correct password:



The password is four digits from 0 to 9; the initial password is “ 0000 “.



Delete current position number

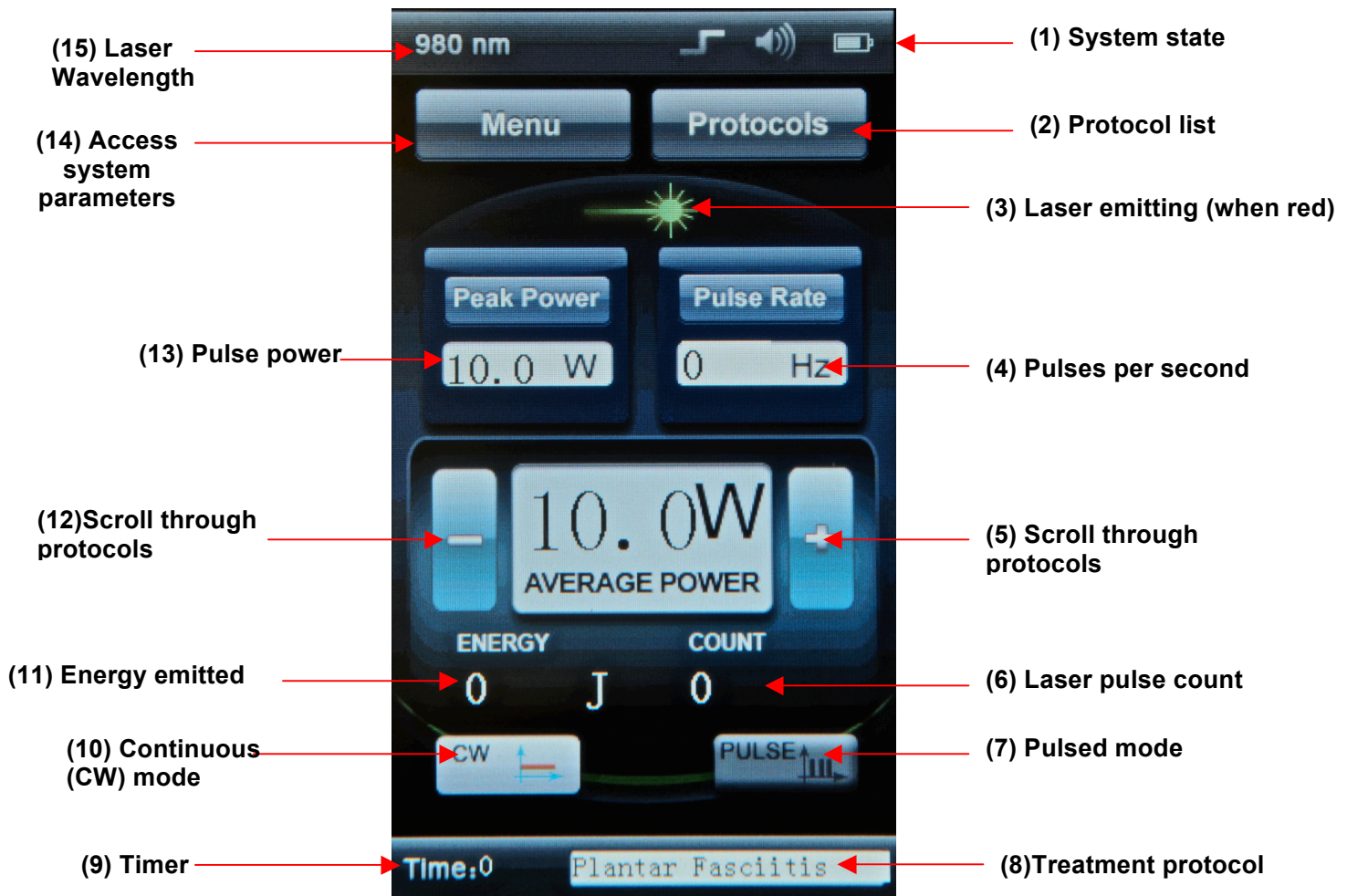


Cancel all input numbers and clear all the input numbers



Confirm the input password

When the correct password is provided, the system will display the main interface screen.

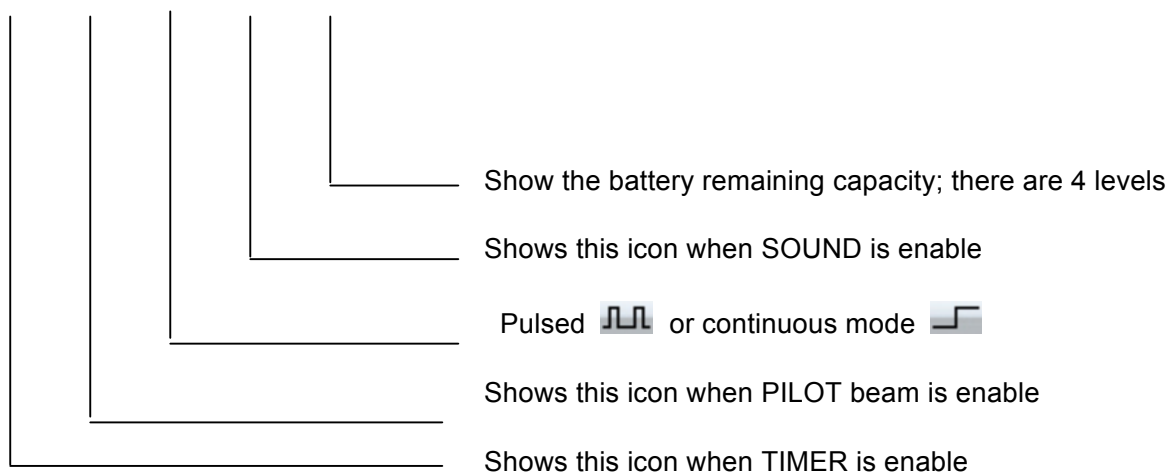


Main Interface Screen

- 1) **System state bar** – displays status of system parameters (see below)
- 2) **Protocols** – access the list of protocols
- 3) **Laser emitting** – when Laser emitting LED light turns to red color
- 4) **Pulse Rate** – displays the number of pulses per second
- 5) **“+” Symbol** – to directly scroll through the list of protocols
- 6) **Laser pulse count** – displays the total laser pulses emitted
- 7) **Pulse mode** – select the pulsed emission mode
- 8) **Treatment Protocol** - displays the current treatment protocol in use
- 9) **Timer** – when the timer is active, the time counts down, otherwise the time counts up
- 10) **Continuous Wave (CW) mode** – select the continuous emission mode
- 11) **Energy emitted** – continuously displays the energy emitted
- 12) **“-” Symbol** – to directly scroll through the list of protocols

- 13) **Pulse power** – displays the laser peak power
- 14) **Menu** – to access the screen to change system parameters and Custom Pulse
- 15) **Laser wavelength** – 980nm

System state bar – Show the option status as depicted below:



6.3 Description of the laser operation

The **Nexus 10W** has two modes of operation: CONTINUOUS and PULSE MODE.

CONTINUOUS MODE - the laser will deliver output radiation at the power level specified by the user as long as the foot or hand switch is depressed.

PULSE MODE - the laser will deliver output radiation according to the power level, number of pulses and pulse format (On Time / Off Time) specified by the user in the Custom Pulse screen.

The pulsed format will be repeated as long as the foot or hand switch is held down up to the number of pulses as specified by the user. If the foot or hand switch interrupts a pulse train the Pulsed mode will be repeated after the foot or hand switch is depressed again.

NOTE: if the system timer is enable, holding down the foot or switch only one time and then released, the laser will deliver output radiation at the power level specified by the user until the timer times out. If the operator holds down the foot or hand switch again, the laser output will be paused until the operator holds down the foot or hand switch again. The timer count is also stopped.

6.3.1 User Interface

The Nexus 10W has two ways to operate the menu: touch screen and using function keys.

6.3.1.1 Touch screen: using touch screen, one can change some parameters directly.



NOTE:

Do not touch the screen with any sharp materials.

Cautions have to be taken that liquids do not come into contact with the surface of the touch screen.

6.3.1.2 Function keys:

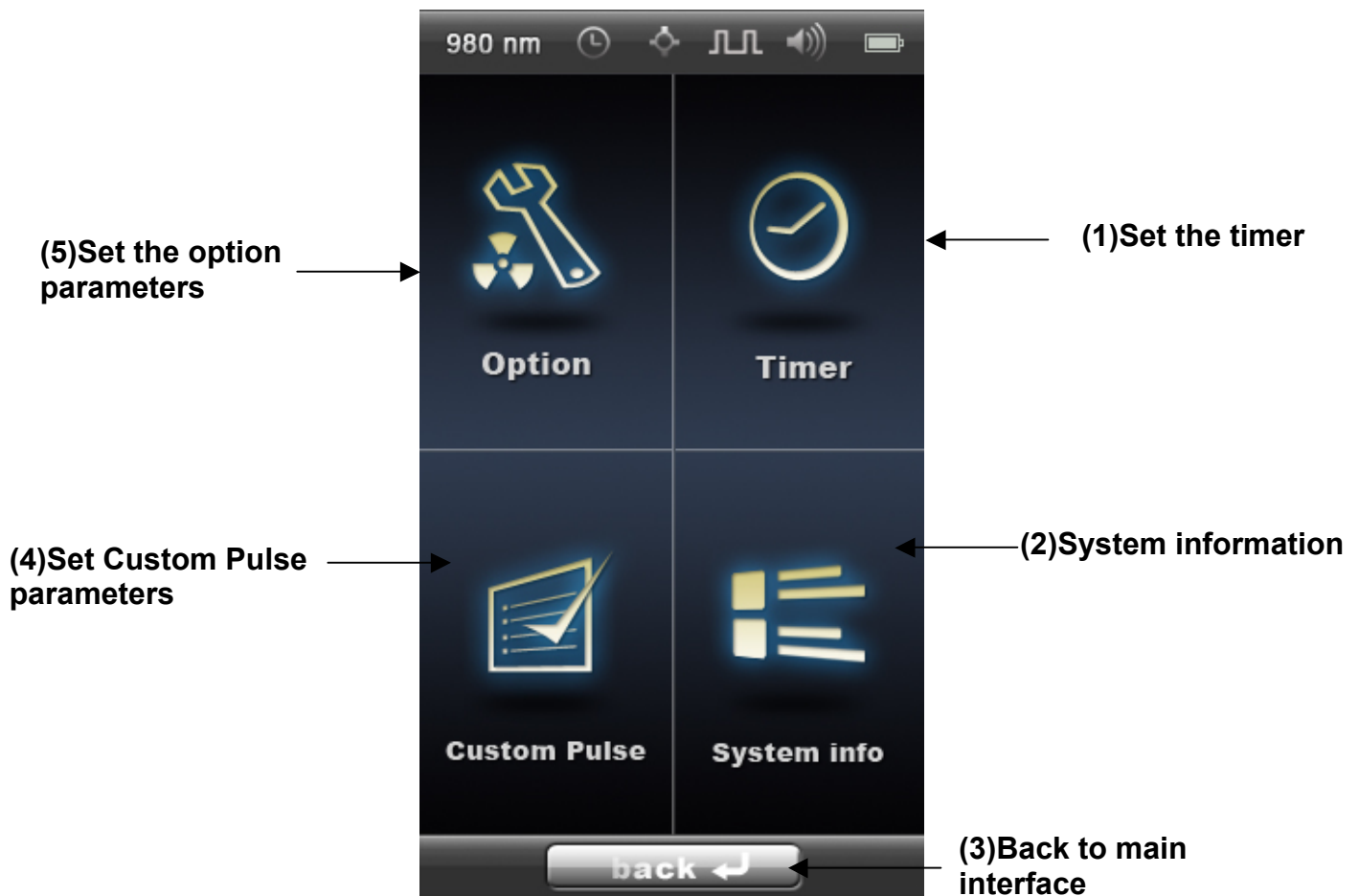


There are 6 keys on the panel:

- STANDBY
- READY
- LEFT
- RIGHT
- UP
- DOWN
- ENTER

6.3.2 Setup laser parameters

At the main interface, Press the “Menu” or the “Enter” function key; you will enter the setup interface:



(1) Set the timer –set the timer’s count time value

(2) System information –give the system information

(3) Back to main interface -back to main interface

(4) Set Custom Protocol parameters –To select a treatment protocol. There are 10 pre-programmed protocols that can be selected. The user can create & program one protocol. Any of the protocol values can be changed.

(5) Set the system parameters - to set system options:

- Pilot light beam intensity

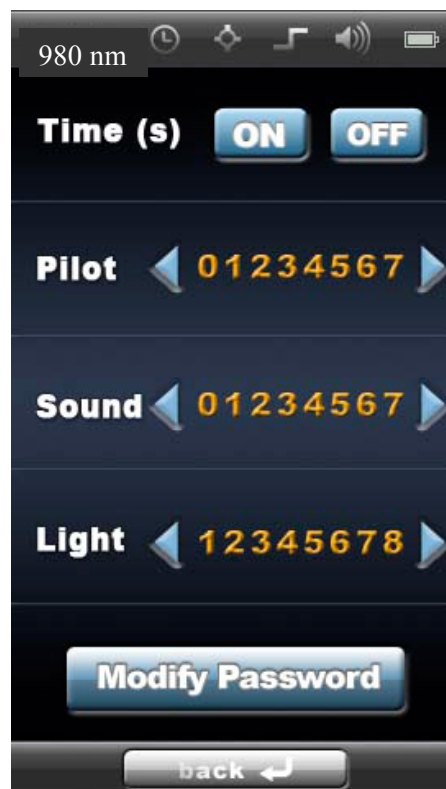
- Sound intensity
- Timer enable or disable
- LCD backlight contrast
- Modify password

6.3.2.1 Use function key in this interface

In this interface, you can choice what you want change. To change the option by pressing the “LEFT” and “RIGHT”, “UP” and “DOWN” key. To confirm, you can press the “ENTER” key.

6.3.3 Set options

When you select “Option” button, you can set the system parameters. To change the option value by press the “LEFT” and “RIGHT”. Change the option with the “UP” and “DOWN” keys. Press the Enter key to confirm.



6.3.4 Set the timer



Use the “UP” and “DOWN” key to change the value of the time, use the “LEFT” and “RIGHT” key to change the selected position. The range of the time is 1 to 9999 seconds.

6.3.5 Select treatment protocol



Use the “UP” and “DOWN” key to change the selected item. When the item is selected, it will highlight. When an item is selected use the “ENTER” key to confirm. The system will load the protocol parameters into the main interface.

6.3.6 System information



The above interface shows the following information:

- Type
- Serial number
- The internal IR Laser source module registration number
- Laser wavelength
- Laser maximum average power
- The manufacturing date

6.3.7 Laser emission

After selecting the laser parameters press the “READY” key in the main interface screen and then hold down the foot or hand switch to start laser emission.

6.3.8 Pulsed Mode Using Custom Pulse (Advanced Users)

In the Main Screen press the Menu button to access the Custom Pulse option. The pulse format is defined by the pulse’s On Time (pulse width in milliseconds) and Off Time (the dark time period between pulses in milliseconds).

The Average Power and Pulse Rate are calculated by the internal computer based on the Peak Power, Ton and Toff values selected. Press the OK button to load the Custom Pulse parameters into the Custom Pulse protocol. Press the Back button to return to the main screen.

To access the Custom Pulse settings, select the Custom Pulse protocol in the screen with the protocol list (last item in the list).



Custom Pulse Screen

6.4 Powering down system

The laser can be switched off by “main power switch”.

NOTE: before you power down the system, you must place the Nexus 10W to “STANDBY” status.

7 Accessories

7.1 Protective glasses

Note: The operator and patient must wear protective goggles when the laser is in operation.

Make sure to use only glasses with an effective optical density around the wavelength of 980nm +/-10nm.

7.2 Power supply

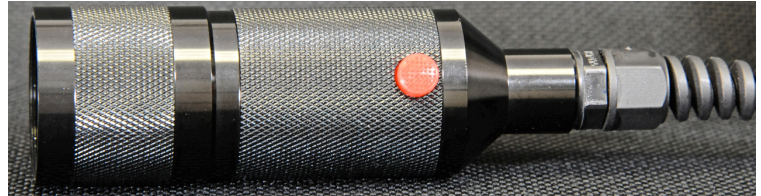
DC26V/4A. Use SINPRO MPU100-102 desktop power supply adapter or equivalent.

7.3 Foot and hand switches

IP68 level or equivalent



Footswitch



**Handpieces with
built-in Switch**

7.4 Handpiece



Note: When the handpiece is not in use, place the handpiece on a secure resting place. The handpiece must not be allowed to fall in order to avoid damage to the optical fiber.

8 Application systems and light delivery systems

8.1 Application systems

The following application systems are approved for the use with **Nexus 10W** laser:

The fiber parameter must satisfy the following:

- Fiber core diameter: at least 400 μm
- $\text{NA} \geq 0.22$
- With SMA 905 connector
- Fiberoptic cable must be inspected for damage

8.2 Handling and use of application and light delivery systems



Attention: The clinical rules concerning the use of medical laser probes must be followed. CBN is not liable for accidents or damage to the laser system resulting from violations of the above-mentioned rules.

To ensure the proper and safe use of laser systems, only trained licensed practitioners should use the approved applications and laser light delivery systems.



Warning: Pay attention to the application instruction for the application and laser light delivery systems.

Check the packaging of the IR Laser fiber optic for possible damage. IR Laser fibers delivered in damaged packaging should not be used.



Warning: To avoid damage to the laser probe, do not hit on a hard surface or over bend the fiberoptic cable.

- Make sure laser is “Off” or in “Standby” mode prior to inserting the fiber into the laser aperture port.
- Insert the fiber into laser aperture port until fully engaged. Make sure the IR Laser probe is screwed in correctly otherwise the security switch in the SMA connector will not be activated and an error message will be displayed.
- Handle the fiber with care as damage may occur if struck or bent sharply.

9 The Lithium-ion battery



Warning: Do not damage the Li-ion battery. A damaged battery can cause an explosion or fire, and can result in personal injury and/or property damage.

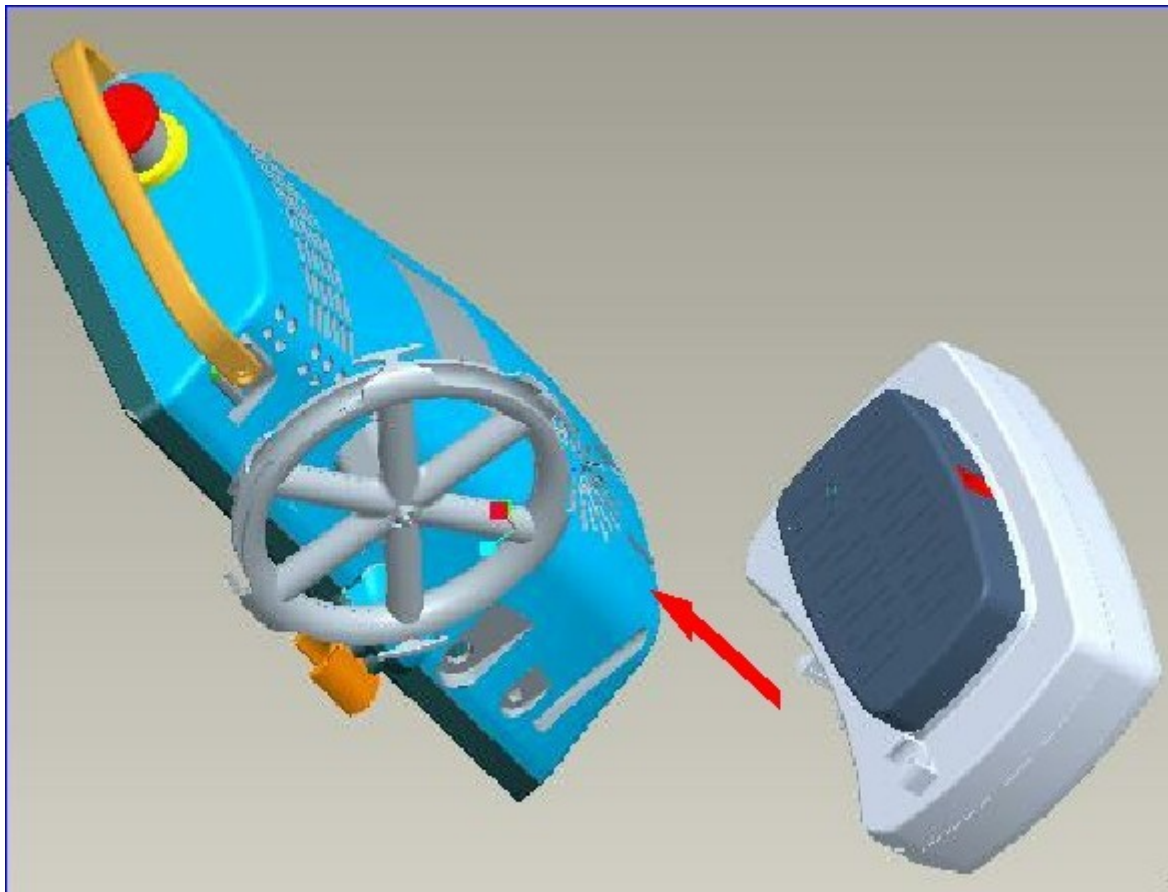
9.1 Rechargeable battery

- 24.2V/4A
- Nominal capacity 2.2AH
- Chargeable Li-Ion battery
- Maximum continuous charge Current 2A
- Discharge current >4A
- Size 65mm×115mm×20mm (H×W×D)

NOTE:

Charge the battery for at least 8 hours prior to the first time of use.

9.2 Change the battery



Install the battery to the main body along the red arrow.

10 Safety

10.1 Safety elements



Attention: Safety-elements are part of the laser system. They must be used to increase the safety in using the **Nexus 10W** with applications systems or light delivery systems/medical probes in a treatment. Check that the safety-elements are working well.

10.2 Possible risk

Burning and swelling of the target tissue can occur if the laser energy applied is too high.

All these potential complications can be avoided if the user is properly trained.

11 Maintenance

The **Nexus 10W** has been designed to operate reliably with a minimum of maintenance.

Note: This unit contains no user serviceable parts. Any attempt to repair, adjust, or modify the system beyond those procedures outlined in this manual by any person not authorized by CBN will invalidate the warranty. CBN reserves the right, in its sole discretion, to decide on warranty voidance.

To prevent the risk of electric shock, do not remove the cover. Qualified personnel should perform all servicing. If service is required, contact a factory service representative.

11.1 Routine maintenance

The following checks should be carried out regularly by the operator:

- Check IR Laser's safety goggles (right type, mechanically undamaged)
- Check all labels are firmly in place
- Check the emergency switch
- Check that disconnection of remote interlock causes the laser to be inoperable and to indicate error message "interlock open"
- Check audible signal is active when foot or hand switch is depressed and laser emission is present
- Check that display indicates error message "Fiber not connect", laser goes into and remains in standby mode when removing fiber optical handpiece from fiber connector port.
- Check that when fiber is removed from laser aperture, laser goes into and remains in standby mode.

In case unit fails any of the aforementioned tests, do not use device for further treatments but call CBN service immediately.

Storage conditions: Temperature: -10° to +50°C Humidity: 80% RH non condensing

Operating conditions: Temperature: +10° to +40°C (In order to better heat dissipation, it is recommended to use temperature of 10-35 °C)
Humidity: 30-50% RH

11.2 Cleaning



Warning: Before cleaning and disinfection of the unit, disconnect the laser from the power supply. Do not use water as it may infiltrate into the equipment.

The housing of the laser can be cleaned with a wet cloth. A mild antiseptic detergent or a mild cleaning agent may be used. Chemical cleaning agents, strong cleaning agents, and rough cleaning cloths can damage the surface of the housing and therefore should not be used.

11.3 Planned preventative maintenance

A CBN -approved technician or other approved personnel should check the **Nexus 10W** IR Laser annually and the results of the maintenance should be recorded in the instrument logbook. See also the section Annual Maintenance. Failure to use a CBN or other authorized CBN personnel during the warranty period will result in the warranty being invalid.

12 Service policy

CBN will make available on request schematic interaction diagrams, component part lists, descriptions and other information that will enable appropriately qualified technical personnel to carry out first line maintenance on the **Nexus 10W**. When parts are deemed to be irreparable by CBN or when special training/equipment are required to perform the repair or adjustments, the manufacturer reserves the right to withhold information on the grounds of safety.

In case of returning the **Nexus 10W** to CBN, use its original packaging.

13 Environmental protection

When the service life of **Nexus 10W** is used up, the laser can be disposed of as the conventional electric products. The device causes no known environmental risks.



14 Warranty policy

CBN warrants the **Nexus 10W** laser system against defects in material and workmanship for a period of 24 months, which will commence on the date of delivery to customer. Warranty extension plans will be made available during the warranty period.

Note: Any attempt to repair, adjust or modify the system beyond those procedures outlined in this manual by any person not authorized by CBN will invalidate the warranty. The warranty will also void in case of:

- Incorrect handling/ mishandling of the laser
- Using components not approved by CBN
- Using non-authorized application systems

Prerequisite for warranty is giving a feedback by using the customer feedback card or Internet:

Web: <http://www.ClearlyBeautifulNails.com>

To make a warranty claim, the purchaser shall promptly contact CBN in writing or by telephone following discovery of the basis of the claim.

During the warranty period CBN, in its sole discretion, will repair or replace components, which are verifiably damaged or malfunctioned.

In no event shall CBN be liable for direct, indirect, special, incidental or consequential damages whether based on contract, tort or any other legal theory.

For further Information contact:

CBN Inc.
1759 Country Club Drive
Cherry Hill, New Jersey 08003

TEL: 856-354-6105

FAX: 866-275-0516

E-mail: Michael@ClearlyBeautifulNails.com

15 ATTACHMENT

15.1 Device Master Record

DEVICE MASTER RECORD			
Model:		Operator:	
S/N:		Location:	
Inventory-No.:			

15.2 Training

Responsible: Name / Signature:	
Date:	
Checked:	
Name of person trained / signature:	

15.3 Annual Maintenance

[illegible]

1.	Visual Inspection	Passed	Failed	Comment
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1.1	Laser labels/warning (IR Laser class, max. power, wavelength) cp. Section Labels			
1.2	All labels are firmly in place cp. Section Labels			
1.3	User manual			
1.4	Equipment complete			
1.5	Ports			
1.6	Outer device surface			
2.	Inspection of functional capability			
2.1	Foot & hand switches			
2.2	Optical Input/ Output /Aiming Beam			
2.3	Interlocks			
2.4	Display and Key Pad			
3.	Inspection of Monitoring and Safety System			
3.1	IR Laser Safety Goggles			
3.2	Control LED			
3.3	Main power switch			
3.4	Emergency stop			
4.	Electrical safety VDE 0750 / VDE 0751			
4.1	Insulation resistance			
4.2	Ground leakage current			mA
4.3	Protective conductor continuity			
5	Measurement of Output Parameters Relevant to Safety			



CAUTION: Always wear laser safety goggles when performing the above procedures.

Laser Calibration Test:

Connect a new CBN handpiece to the output port of the IR Laser. Put the distal end of the

handpiece into a laser power meter. Enable the laser, fire the laser and record the values displayed on the laser power meter.

Place the IR Laser into Continuous Mode. Fire the IR Laser and verify with the power meter that the output is within the tolerances					
Power Selected		Power selected Value (W) +/-20% Min / Max	Actual Value	Passed	Failed
1 W		0.8 - 1.2			
2 W		1.6 - 2.4			
3 W		2.4 - 3.6			
4 W		3.2 - 4.8			
5 W		4.0 - 6.0			
6 W		4.8 - 7.2			
7 W		5.6 - 8.0			

If the results fall within the expected 20% range, then the laser is deemed calibrated. No further action is needed.



CAUTION: If the laser falls outside the 20% range, then CBN or an authorized representative should be contacted.

5.	Measurement of Output Parameters Relevant to Safety	Passed	Failed	Comment
5.1	Result according to 5.			
6.	Inspection of Internal Error Messages			
6.1	Interlock			
6.2	Excess Temperature Indication: Inspection via Software			



Warning: In case of any parameters relevant to safety failing the annual maintenance, stop using the device immediately.

Actions taken:			
Service informed		Device retired on:	

Clearly Beautiful Nails LLC
Nexus 10W



on:			
Device repaired on:		Entry in Instrument Logbook:	
Inspector:			
Notes:			
Status:	Date:	Inspector:	